

matter. The Office Action states that the claims can embrace cells within a human that have been infected with the adenovirus vector of the invention. Without conceding to the correctness of the rejection, Applicants have amended Claims 82-83 to recite an *in vitro* host cell, which cannot encompass cells within a human.

Claims 54, 56, 58-63, 66, 70, 72-83, 104-107 have been rejected under 35 U.S.C. 112, first paragraph. The Office Action states that the term "uroplakin II (UPII) transcriptional response element encompasses homologs of the human or murine regulatory elements taught in the instant specification that are obtained from alternative sources, and would include any enhancer element that regulates expression of the uroplakin II gene that are not homologous to the provided sequences. Without conceding to the correctness of the rejection and without prejudice to the refilling of claims of the original scope, Applicants have amended independent Claims 54 and 70 to recite specific sequences set forth in the specification and sequence listing. Withdrawal of the rejection is requested.

Claims 1-5, 56, 58-61, 63-65 and 78-79 have been rejected under 35 U.S.C. 112, second paragraph.

Claim 1 has been rejected as indefinite in the recitation of "2028" and "2239" without reference to units. Claims 1-5 and 64-65 have been rejected as indefinite in the recitation of the term "comprising about". Claims 56 and 61 have been rejected as indefinite in the recitation of the term "the adenoviral gene". Claims 63 and 66 have been rejected as dependent on a cancelled claim. Claims 63, 66 and 78-79 have been rejected as indefinite in the recitation of the term "derived from".

The rejected claims have been amended in accordance with the Examiner's suggestions. Withdrawal of the rejections is requested.

CONCLUSION

Applicants submit that all of the claims are now in condition for allowance, which action is requested. If the Examiner finds that a Telephone Conference would expedite the prosecution of this application, she is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any other fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, order number CELL-016.

Respectfully submitted,

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APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (amended) An isolated human uroplakin II (UPII) transcriptional regulatory element (TRE) comprising [about] nucleotides 2028 to [about] 2239 of SEQ ID NO:1, wherein said [polynucleotide] TRE exhibits urothelial cell-specific [TRE] activity.

2. (amended) The [polynucleotide] UPII TRE of claim 1, comprising nucleotides [about] 1647 to [about] 2239 of SEQ ID NO:1.

3. (amended) The [polynucleotide] UPII TRE of claim 1, comprising nucleotides [about] 1223 to [about] 2239 of SEQ ID NO:1.

4. (amended) The [polynucleotide] UPII TRE of claim 1, comprising nucleotides [about] 1 to [about] 2239 of SEQ ID NO:1.

5. (amended) The [polynucleotide] UPII TRE of claim 1 comprising nucleotides [about] 430 to [about] 2239 of SEQ ID NO:1.

54. (twice amended) An adenovirus vector comprising an adenoviral gene essential for replication under transcriptional control of a uroplakin II (UPII) transcriptional response element (TRE) comprising a nucleotide sequence selected from the group consisting of nucleotides 2028 to 2239 of SEQ ID NO:1; nucleotides 1647 to 2239 of SEQ ID NO:1; nucleotides 1223 to 2239 of SEQ ID NO:1; nucleotides 1 to 2239 of SEQ ID NO:1; nucleotides 430 to 2239 of SEQ ID NO:1; nucleotides 2023-2239 of SEQ ID NO:2, nucleotides -587 to +1 of SEQ ID NO:2; and -965 to +1 of SEQ ID NO:2.

56. (amended) An adenovirus vector according to claim 54, wherein the adenoviral gene essential for replication is an adenoviral early gene.

61. (amended) An adenovirus vector according to claim 54, wherein the adenoviral gene essential for replication is an adenoviral late gene.

63. (amended) An adenovirus vector according to claim [62] 54, wherein the uroplakin gene

TRE is [derived] obtained from a mouse uroplakin II gene.

64. (amended) An adenovirus vector according to claim 63, wherein the TRE comprises nucleotides [about] -587 to [about] +1 of SEQ ID NO:2.

65. (amended) An adenovirus vector according to claim [63] 54, wherein [the] said TRE comprises nucleotides [about] -965 to [about] +1 of SEQ ID NO:2.

66. (amended) An adenovirus vector according to claim [62] 54, wherein the uroplakin II TRE is [derived] obtained from a human uroplakin II gene.

68. (amended) An adenovirus vector according to claim 54, wherein said TRE comprises nucleotides 2023-2239 of [Fig. 1] SEQ ID NO:2.

70. (amended) An adenovirus vector comprising

(a) an adenovirus gene essential for replication under transcriptional control of a uroplakin II transcriptional regulatory element (TRE) comprising a nucleotide sequence selected from the group consisting of nucleotides 2028 to 2239 of SEQ ID NO:1; nucleotides 1647 to 2239 of SEQ ID NO:1; nucleotides 1223 to 2239 of SEQ ID NO:1; nucleotides 1 to 2239 of SEQ ID NO:1; nucleotides 430 to 2239 of SEQ ID NO:1; nucleotides 2023-2239 of SEQ ID NO:2, nucleotides -587 to +1 of SEQ ID NO:2; and -965 to +1 of SEQ ID NO:2; and

(b) an E3 region.

78. (twice amended) The adenovirus vector according to claim [77] 70, wherein the uroplakin II TRE is [derived] obtained from a mouse uroplakin II gene.

79. (twice amended) The adenovirus vector according to claim [77] 70, wherein the uroplakin II TRE is [derived] from a human uroplakin II gene.

82. (amended) An in vitro host cell comprising the adenoviral vector of claim 54.

83. (amended) An in vitro host cell comprising the adenoviral vector of claim 70.